APPENDIX

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

[Nov. 16, 1984]

Dear Sir or Madam:

We are sending you this letter as part of an effort to keep interested persons informed in a timely manner as to the Food and Drug Administration's policies, implementation procedures and interpretations with respect to the Drug Price Competition and Patent Term Restoration Act. This information is provided as a supplement to my October 11, 1984 letter which you should have received, and is in the format of questions that we have received and answers that we have given to those questions.

* * * *

7. Q. What type of bioequivalence requirement will be imposed on the ANDAs for drugs first approved after 1962?

   A. *In vivo* data will be required for single-source and post-1962 drugs until such time as a correlation between *in vivo* and *in vitro* standards can be established for individual drugs. *In vivo* requirements will also be continued on other drugs where they are currently imposed. Of course, waivers from bioequivalence studies may be granted for dosage forms and routes of administration that are by their nature bioequivalent (e.g., intravenous solution).

8. Q. Under the DESI program, certain drugs that posed methodology problems were granted a de-

ferral of the bioequivalence requirements. Will this policy continue?

A. The new statute appears not to permit deferrals of bioequivalence requirements. Therefore, demonstration of bioequivalence, whether *in vivo* or *in vitro*, will be required for all drugs.